PTO/SB/21 (09-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE he Paper Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/805,788 TRANSMITTAL Filing Date Mar 22, 2004 **FORM** First Named Inventor Quay, Steven C. **Art Unit** 1614 (to be used for all correspondence after initial filing) **Examiner Name** Attorney Docket Number Total Number of Pages in This Submission 03-04US **ENCLOSURES** (Check all that apply) After Allowance communication to (TC) Fee Transmittal Form Drawing(s) Appeal Communication to Board of Fee Attached Licensing-related Papers Appeals and Interferences Appeal Communication to TC Amendment / Reply Petition (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final **Proprietary Information** Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please identify Terminal Disclaimer Х **Extension of Time Request** below): **Express Abandonment Request** Request for Refund 1) Form 1449A (3 pgs) Information Disclosure Statement CD, Number of CD(s) _ 2) International Search Report (Spgs) Landscape Table on CD 3) Foreign References (181 pgs) Certified Copy of Priority Document(s) Remarks Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Nasteph Pharmaceutical Company Inc. Signature Printed name Deter J. Knudsen 40682 Date August 19, 2005 Reg. No.

CERTIFICATE OF TRANSMISSION/MAILING					
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Signature	Settent 1	Trans			
Typed or printed name	Jeffrey J. Granner			Date	August 19, 2005
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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Apphicant(s): Quay et al.

Group Art Unit: 1614

Serial No.: 10/805,788

Attorney Docket No.: 03-04US

Filed: 3/22/2004

Title: NASAL CALCITONIN

FORMULATIONS CONTAINING

CHLOROBUTANOL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted:

X	(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
	under 37 CFR 1.97(c) together with either a: Statement under 37 CFR 1.97(e), or a \$180.00 fee under 37 CFR 1.17(p), or (After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
_	under 37 CFR 1.97(d) together with a: Statement under 37 CFR 1.97(e), and a \$180.00 fee set forth in 37 CFR 1.17(p). (Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

X Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

I hereby certify that this Correspondence is being deposited with the United States Postal service with sufficient postage for first class mail in an envelope address to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or the correspondence is being facsimile transmitted to the USPTO, on the date indicated below.

Date of Deposit: August 19, 2005

Typed Name: Jeffrey L. Granger

Signature:

Respectfully submitted,

Peter J. Knudsen

Attorney/Agent for Applicant(s)

Reg. No. 40682

Date: August 19, 2005

Telephone No.: 425-908-3643

PTO/SB/08a (08-03)

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rk Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known Substitute for form 1449A/PTO 10/805,788 Application Number INFORMATION DISCLOSURE 3/22/2004 Filing Date STATEMENT BY APPLICANT First Named Inventor Quay et al. **Art Unit** 1614 (Use as many sheets as necessary) **Examiner Name** of 3 Attorney Docket Number 03-04US Sheet 1

			U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-4,670,419	Issued 06-02-1987	Takeda Chemical Industries, Ltd.	
		US-4,690,952	Issued 09-01-1987	Yamanouchi Pharmaceutical Co., Inc.	
···············		US-4,788,221	Issued 11-29-1988	Yamanouchi Pharmaceutical Co., Ltd.	
		US-4,985,242	Issued 01-15-1991	Teljin Limited	
		US-4,988,512	Issued 09-18-1989	Sandoz Ltd.	
		US-5,026,825	Issued 06-25-1991	Rhone-Poulenc Rorer Pharmaceuticals, Inc.	
		US-5,059,587	Issued 10-22-1991	Toyo Jozo Company, Ltd.	
		US-5,091,365	Issued 02-25-1992	Hoechst Aktiengesellschaft	
		US-5,112,804	Issued 05-12-1992	Temple University of the Commonwealth System of Higher Education	
		US-5,124,315	Issued 06-23-1992	Phideatech S.R.L.	
		US-5,153,308	Issued 10-06-1992	Teijin Limited	
		US-5,179,079	Issued 01-12-1993	Novo Nordisk A/S	
		US-5,183,802	Issued 02-02-1993	ISF Societa per Azioni	
		US-5,200,393	Issued 04-06-1993	The Liposome Company, Inc.	
		US-5,204,108	Issued 04-20-1993	Danbiosyst UK Ltd.	
		US-5,211,950	Issued 05-18-1993	Teijin Limited	
		US-5,215,739	Issued 06-01-1993	Toko Yakuhin Kogyo Kabushiki Kaisha	
		US-5,281,580	Issued 01-25-1994	Toyo Jozo Company, Ltd.	
		US-5,321,008	Issued 06-14-1994	Amylin Pharmaceuticals, Inc.	
		US-5,428,006	Issued 06-27-1995	Bechgaard International Research and Development A/S	

	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ - Number* - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т6
	†	FR 2.205.308	05-31-1974	Farbwerke Hoechst AG		1
	1	EP 0 111 841 A1	06-27-1984	Syntex (U.S.A.) Inc.		
		EP 0 115 627 A1	08-15-1984	Armour Pharmaceutical Company		
		EP 0 183 527 B1	06-04-1986	Yamanouchi Pharmaceutical Co. Ltd.		
		EP 0 193 372 A2	09-03-1986	Teijin Limited		

Examiner	Date	
Signature	Considered	

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duction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Substitution 1449A/PTO Complete if Known 10/805,788 Application Number INFORMATION DISCLOSURE 3/22/2004 Filing Date STATEMENT BY APPLICANT First Named Inventor Quay et al. Art Unit 1614

(Use as many sheets as necessary) **Examiner Name** Sheet 2 of 3 Attorney Docket Number 03-04US

_			U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,428,706	Issued 6-27-1995	Coflexip	
		US-5,482,931	Issued 01-09-1996	Ferring AB	
	<u> </u>	US-5,503,827	Issued 04-02-1996	Boehringer Mannheim GmbH	
	<u> </u>	US-5,508,260	Issued 04-16-1996	Amylin Pharmaceuticals, Inc.	
	Ţ	US-5,514,365	Issued 05-07-1996	Schiapparelli Salute S.P.A.	
	T T	US-5,527,771	Issued 06-18-1996	Amylin Pharmaceuticals, Inc.	
		US-5,554,378	Issued 09-10-1996	Takeda Chemical Industries, Ltd.	
		US-5,565,423	Issued 10-15-1996	Hoechst Aktiengesellschaft	
		US-5,574,006	Issued 11-12-1996	Dott Research Laboratory	
		US-5,576,016	Issued 11-19-1996	Pharmos Corporation	
		US-5,578,324	Issued 11-26-1996	Teijin Limited	
		US-5,603,943	Issued 02-18-1997	Dott Research Laboratory	
	I	US-5,654,000	Issued 08-05-1997	Poli Industria Chimica S.p.Al	
		US-5,681,811	Issued 10-28-1997	Protein Delivery, Inc.	
		US-5,693,608	Issued 12-02-1997	Bechgaard International Research and Development A/S	
		US-5,719,122	Issued 02-17-1998	SmithKline Beecham Farmaceutici S.p.A.	
		US-5,725,852	Issued 03-10-1998	Takeda Chemical Industries, Ld.	
		US-5,725,871	Issued 03-10-1998	Danbiosyst UK Limited	
	T	US-5,733,569	Issued 03-31-1998	Novartis Corporation	

	FOREIGN PATENT DOCUMENTS					
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Т6
Initials*	No.1	Country Code ³ - Number - Kind Code ⁵ (if known)	WINI-50-1111		or Relevant Figures Appear	$oxed{oxed}$
		GB 2 177 914 A	02-04-1987	Chugai Seiyaku Kabushiki Kaisha		
		EP 0 358 234 A2	03-14-1990	Rorer International (Overseas) Inc.		
		EP 0 371 010 A1	05-30-1990	Yamanouchi Pharmaceutical Co. Ltd.		
		EP 0 418 697 A1	03-27-1991	Esseit s.a.s. Laboratorio Chimico Farmaco Biologico Di A. Ievoli & C.		
		EP 0 471 618 A1	08-12-1991	Toyo Jozo Co., Ltd.		
		EP 0 489 217 A1	06-10-1992	DR. A Tosi Farmaceutici S.R.L.		

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Application Number 10/805,788

Filing Date 3/22/2004

First Named Inventor Quay et al.
Art Unit 1614

Examiner Name

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Sheet

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	_		U.S. PATENT	DOCUMENTS	
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		US-5,759,565	Issued 06-02-1998	Novartis Corporation	
***************************************		US-5,859,048	Issued 01-12-1999	Teikoku Hormone MFG. Co., Ltd.	
		US-5,948,749	Issued 09-07-1999	Fuji Yakuhin Company, Limited	
		US-6,078,338	Issued 07-11-2000	Therapicon S.R.L.	
		US-6,149,893	Issued 11-21-2000	Alfa Wasserman S.p.A.	
		US-6,161,731	Issued 12-19-2000	Novartis AG	
		US-6,174,857 B1	Issued 01-16-2001	Novartis Corporation	
		US-6,221,367 B1	Issued 04-24-2001	Emisphere Technologies, Inc.	
		US-20020010428 A1	01-24-2002	Vedrine, Lionel; et al.	
		US-20020012688 A1	01-31-2002	Dohi, Masahiko; et al.	
		US-20020015737 A1	02-07-2002	MacroMed, Incorporated	
		US-20020031558 A1	03-14-2002	Yoo, Seo Hong	
		US-20020037836 A1	03-28-2002	Henriksen, Dennis Bang	
·		US-20020068092 A1	06-06-2002	Bosch, H. William; et al.	
		US-20020076441 A1	06-20-2002	MacroMed, Inc.	
		US-20020107265 A1	08-08-2002	Chen, Feng-Jing; et al.	
		US-20020110525 A1	08-15-2002	Adjei, Akwete L.; et al.	
		US-20020110527 A1	08-15-2002	Zhu, Yaping; et al.	
		US-20020110528 A1	08-15-2002	Zhu, Yaping; et al.	

	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т6
		WO 99/16427 (Int. App. No. PCT/US98/20548)	04-08-1999	Emisphere Technologies, Inc.		
						<u> </u>

Examiner	Date	
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